K001474

JUN - 9 2000

# SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

**Device Name:** **TERUMO® U-100 Insulin Syringe**

**Classification Name:** **Piston syringe with fixed hypodermic single lumen needle**

## INTENDED USE

The TERUMO ® U-100 Insulin Syringe with fixed hypodermic single lumen needle, is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended particularly for the aspiration and injection of insulin. This syringe with 30G needle is indicated for general use and for pediatric patients.

## DESCRIPTION

The TERUMO ® Insulin Syringe is a sterile, single use piston syringe with a fixed hypodermic single lumen needle, designed for manual use. The syringe is available in 1/2cc and 3/10cc volumes with a 30 gauge by 3/8 inch fixed hypodermic single lumen needle. The 3/10 cc syringe includes 1/2 unit markings.

## SUBSTANTIAL EQUIVALENCE

The TERUMO ® Insulin Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared TERUMO ® Insulin Syringe (K992802).

## PRINCIPLE OF OPERATION/TECHNOLOGY

This device is operated manually.

## MATERIALS

The materials used in this device are the same as used in the predicate.

## PERFORMANCE

The performance of this device is equivalent to the predicate.

## CONCLUSION

The TERUMO® U-100 Insulin Syringe submitted in this Premarket notification is substantially equivalent to the TERUMO ® Insulin Syringe (K992802) with respect to intended use, design, technology/principles of operation, materials and performance. Differences between the devices do not raise any new issues of safety or effectiveness.

Date Prepared: 5/1/00

Prepared by: Sandi Hartka
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Elkton, MD 21921
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2000

Ms. Sandi Hartka
Terumo Medical corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K001474
Trade Name: Terumo U-100 Insulin Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 7, 2000
Received: May 11, 2000

Dear Ms. Hartka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001474

**510(k) Number (if known):**

**Device Name:** TERUMO® U-100 Insulin Syringe – Pediatric Indication

**Indications For Use:**

The TERUMO® U-100 Insulin Syringe with fixed hypodermic single lumen needle is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device in intended particularly for the aspiration and injection of insulin. This syringe with 30G needle is indicated for general use and for pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

Patricia Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001474

(Optional Format 1-2-96)